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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,650	06/27/2003	Dennis D. Garvin	41097.001	2638

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MADISON, WI 53717-1914

EXAMINER

POUS, NATALIE R

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/607,650

Applicant(s)

GARVIN, DENNIS D.

Examiner

Natalie Pous

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-8, 13, 16 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-8, 13, 16 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All. b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/1/04, 10/15/03.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection based on the amendments to the claims.

Claim Objections

Claim 1 is objected to because of the following informalities: line 10 recites "the mail connector." It is inferred that the correct spelling is --the male connector--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the longitudinal axis" in line 8. There is insufficient antecedent basis for this limitation in the claim. Claims 7, 8, 13, 16 and 17 are subsequently rejected as being dependent from rejected base claim

Claim Rejections - 35 USC § 102

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 6-8, 16 and 17 is rejected under 35 U.S.C. 102(b) as being anticipated by Green et al. (US 4950284).

Regarding Claim 6, Green teaches a wound closure device for connecting tissue (10) comprising at least one pair of isolated first (14) and second (13) flexible straps (it is noted that all materials inherently have some degree of flexibility) wherein:

a. the first flexible strap (14) has a proximal end with a male connector and a distal end (24), and a ventral surface and a dorsal surface (fig. 7); and

b. the second flexible strap (13) has a proximal end with a female connector (19, 22) and a distal end, and a ventral surface and a dorsal surface, wherein the female connector is configured to adjustably connect to the male connector of the first strap (fig. 6), wherein the female connector includes an opening transverse to the longitudinal axis extending completely through the female connector from the ventral surface to the dorsal surface for receiving the male connector (figs. 10), wherein the first strap and the second strap have a plurality of barbs (26, 21) on the ventral surface for engaging the tissue, and whereby the straps form a wound closure (fig. 1)

Regarding Claim 7, Green teaches the device of claim 6, wherein the first strap (14) and second strap (13) are placed in the fascia (12) of the wound (fig. 7)

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Regarding Claim 8, Green teaches the device of claim 6, wherein the device is made of resorbable material (Column 2, proximate lines 10-14)

Regarding Claim 16, Green teaches the device of claim 6 wherein the female end comprises a buckle (17)

Regarding Claim 17, Green teaches the device of claim 16, wherein the male end of the first strap (14) includes a ratcheted surface to accommodate the buckle of the female end (fig. 7)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6-8, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buncke (US 5931855) in view of Sutherland et al. (US 4730615).

Buncke teaches a wound closure device for connecting tissue (20) comprising at least one pair of isolated first and second flexible straps (10) wherein:

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the first flexible strap (10) has a proximal (10b) end and a distal end, and a ventral surface and a dorsal surface (fig. 3); and

the second flexible strap (10) has a proximal end (10b) and a distal end, and a ventral surface and a dorsal surface, wherein the straps are designed to be adjustably connected to each other (fig. 6); wherein the first strap and the second strap have a plurality of barbs (16) on the ventral surface for engaging the tissue, and whereby the straps form a wound closure

wherein the first and second straps are placed in the fascia of the wound (fig. 3)

wherein the device is made of resorbable material (Column 2, proximate lines 55-57)

Buncke fails to teach wherein the ends of the straps comprise a male connector with a ratcheted surface and a female connector with a buckle respectively, and the female connector is configured to adjustably connect to the male connector of the first strap, wherein the female connector includes an opening transverse to the longitudinal axis extending completely through the female connector from the ventral surface to the dorsal surface for receiving the male connector.

Sutherland teaches a device for connecting tissue wherein one end of the device comprise a male connector (18) with a ratcheted surface (22) and the other end comprises a female connector (12) with a buckle, and the female connector is configured to adjustably connect to the male connector, wherein the female connector (12) includes an opening transverse to the longitudinal axis extending completely through the female connector from the ventral surface to the dorsal surface for receiving the male connector (fig. 2) in order to provide a device for closing tissue with a locking

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means to prevent backward movement of the device once it is engaged, and further provide a locking mechanism that avoids problems such as inadequate material strength of the knot tied in the two ends, and takes less time and effort to implement in surgery (column 1, proximate lines 10-20 and 52). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Buncke with the locking configuration of Sutherland in order to provide a device for closing tissue with a locking means to prevent backward movement of the device once it is engaged, and further provide a locking mechanism that avoids problems such as inadequate material strength of the knot tied in the two ends, and takes less time and effort to implement in surgery.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Buncke and Sutherland as applied to claim 6 above, and further in view of Ruff (US 6241747). The combination of Buncke and Sutherland teaches all limitations of preceding dependent claim 6, as previously described, but fails to teach wherein the first and second straps are placed in the wound by the use of a trochar. Ruff teaches a barbed tissue connector for closing wounds in tissue wherein the device is placed in the wound by use a trochar (80) in order to provide additional support to the strap during insertion (Column 6, proximate lines 60-61). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Buncke and Sutherland by using a trochar to insert the straps into the wound as taught by Ruff in order to provide additional support to the straps during insertion.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
2/8/07


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2/14/07